DECLARATION

I, Jeffrey C. Barfield of Alpenrosenstr. 3, 82377 Penzberg, Germany, do hereby declare that I am conversant with the English and German languages and that I am a competent translator thereof.

I verify that the attached English translation is a true and correct translation of the patent application "A probe" with the internal reference number B4009PUS.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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A probe

The present invention relates to an endoluminal probe for radio frequency thermoablation, also called radio frequency induced thermotherapy, in which biological tissues are thermally denatured by heat generation by means of radio frequency electric fields and currents. The probe, which can in particular also be used in combination with the flexible endoscopic technique, serves for the minimally invasive, thermal influencing of diseased structures in hollow organs (e.g. intestine, bronchi, trachea, esophagus) or in larger veins or arteries by radio frequency energy in the frequency range from 300 kHz up to 1 MHz.

It is the object of the invention to provide an endoluminal probe for radio frequency thermoablation which can be manufactured in a cost favorable manner.

This object is satisfied by the features of claim 1 and in particular in that the probe has an insulated hose at whose distal end a metal electrode is provided whose spatial extent can be changed from a cylindrical shape to a star shape. A small lumen navigation of the probe inside a biological lumen or via the instrumentation channel of an endoscope is possible by the cylindrical shape of the metal electrode. After positioning the electrode in the target area, an electrode unfolding can subsequently take place to form the star shape. Particularly good effects are in particular achieved in thermoablation in this process due to the star shape of the electrode, with the changeable diameter of the star-shaped electrode being an additional advantage. A locally defined and electrically conductive electrode contact can hereby be established intraluminally despite an anatomically variable biological environment.

In accordance with the invention, the metal electrode is formed by a plurality of flexible arms whose distal and proximal ends are connected to one another, with the distal and/or the proximal ends of the arms being electrically connected to a terminal for the supply of a radio frequency current. In accordance with the invention, the flexible arms thus themselves form the electrode, i.e. no additional point electrodes or the like are necessary. The manufacture of the probe is hereby simplified, on the one hand. It can be easily cleaned, on the other hand.

After the therapeutic energy application, the unfolding of the metal electrode can be reversed again, whereby a removal of the probe from the hollow space is easily possible.

Advantageous embodiments of the invention are described in the description, in the drawing and in the dependent claims.

In accordance with a first advantageous embodiment, the shape of an arm can differ approximately at its center from its shape at both ends. A bending behavior, which promotes the star-shaped formation of the metal electrode, is hereby pre-determined by the shape of the arm itself. The outer contour of an arm can, for example, be approximately spiral-shaped, zig-zag-shaped, wave-shaped or meander-shaped approximately at its center, with the outer contour being a straight line at the two end regions of the arm. The bending stiffness can be appropriately matched to the requirements by a central region of an arm formed in this manner.

In accordance with a further embodiment of the invention, the distal and proximal ends of the arms can be adjustable relative to one another with the aid of an actuation device provided at a proximal region of the hose.

The outer diameter of the metal electrode can hereby be varied and the spatial extent can be changed from the cylindrical shape to the star shape.

In accordance with a further embodiment of the invention, the proximal ends of the arms are connected to a flexible cannula which is guided inside the hose. This embodiment has the advantage that flushing liquid and/or a further adjustment element for the movement of the arms can be guided inside the flexible cannula. The distal ends of the arms can, for example, be connected to a flexible adjustment element which is guided inside the hose or inside the cannula respectively. In this manner, the outer diameter of the metal electrode can be changed without the hose necessarily being moved along in this process.

In accordance with a further embodiment of the invention, a temperature sensor can be arranged in the region of the distal ends. Such an arrangement additionally allows a temperature control or also an automatic temperature regulation via a radio frequency generator made for this purpose.

It can furthermore be advantageous for a proximal end of the probe to be provided with a connection for flushing liquid. This flushing liquid can be conveyed through the hose or through the cannula provided in the hose in the direction of the metal electrode in order to avoid a drying out and a loss of electrical conductivity in the ablation zone.

An electrode for a probe of the kind described above can be manufactured in an advantageous manner in that an areal blank or a cylindrical cannula of electrically conductive material is provided with micro-cuts which extend parallel to one another and whose ends in each case do not extend up to the rim of the blank or of the cannula. In this manner, individual webs, which serve as arms of the probe, are formed between the micro-

cuts. It can be advantageous in this process for the micro-cuts to be made in spiral form, in meander form, in wave form or in zig-zag form in a central section. Flexurally resilient metal webs are hereby formed in the central region of the arms. To make the central sections of the arms particularly flexible, it can furthermore be advantageous to select the thickness of the micro-sections to be larger in a central section and to be smaller in the end sections.

The present invention will be described in the following by way of example with reference to an advantageous embodiment and to the enclosed drawing. There are shown:

Fig. 1 a schematic view of an apparatus for radio frequency thermoablation;

Fig. 2 a partly sectioned view of a distal end of a probe, in which the metal electrode has a cylindrical shape; and

Fig. 3 the probe of Fig. 2, with the metal electrode having unfolded to form a star shape.

Fig. 1 schematically shows a system for radio frequency thermoablation having a radio frequency generator 10, a neutral electrode 12 and an endoluminal probe 14 at whose distal end a metal electrode 16, shown only schematically, is provided. The metal electrode 16 is located at the distal end of an insulating hose 18 at whose proximal end a hand piece 20 is provided. The hand piece 20 has a terminal for a radio frequency cable 22 which electrically connects the radio frequency generator 10 to the metal electrode 16. The neutral electrode 12 is electrically connected to the radio frequency generator 10 via a neutral electrode cable 24.

Fig. 2 shows in a perspective view the distal region of the probe 14, with the metal electrode 16 being folded together to form a cylindrical shape and being retracted into the interior of the hose 18. Part of the hose 18 is shown open for better illustration.

Fig. 3 shows the probe of Fig. 2, with the metal electrode 16, however, being pushed out of the hose 18 and being unfolded to form a star shape. As can be recognized in Figures 2 and 3, the metal electrode 16 is, for example, formed by six flexible arms 26 which extend coaxially to the axis of the hose 18 in Fig. 2, but which project predominantly radially and in a star-shaped manner from the central axis of the probe in Fig. 3. All arms 26 are connected to one another at their distal ends via a cup-shaped end piece 28. The distal ends of the arms 26 are likewise connected to one another via a sleeve-shaped end piece 30. The arms 26 and the end pieces 28 and 30, which are all connected to one another in one piece, thus form the metal electrode 16 which can be guided through the instrumentation channel of an endoscope due to its extremely compact construction.

As can in particular be recognized in Figs. 2 and 3, each arm 26 consists of a thin metal strip with a rectangular cross-section, with the shape of each arm 26 differing approximately at its center M from the shape at the two ends of the arm. The outer contour of each arm 26 is made in wave shape approximately at its center M, whereas a section with a straight-line outer contour adjoins the wave-shaped region at both sides at the center M. The section with a wave-shaped outer contour has approximately one third of the total length of the arm 26 in this process.

Due to the wave-shaped outer contour of the arms 26 in their central region M, the arms can be bent into the arrangement shown in Fig. 3, in

which the wave-shaped section has a U-shaped curve and the arms project approximately at right angles from the central axis of the probe. In contrast, the metal electrode 16 in the state shown in Fig. 2 in which it has been retracted into the interior of the hose, has a cylindrical shape in which the individual arms 26 extend parallel to one another and contact one another with only a low spacing.

The proximal end piece 30 of the metal electrode 16 is connected to a flexible cannula 32 which is guided inside the hose and is in communication with a slide handle 34 (Fig. 1) of the hand piece 20. The distal end piece 28 of the metal electrode 16 is connected to a flexible adjustment element 36 which is guided inside the cannula 32 and whose proximal end is in communication with a slide handle 38 which is likewise provided on the hand piece 20. The adjustment element 36 and the cannula 32 are connected in a mechanically releasable manner to the slide handles 34 and 38 inside the hand piece 20, with the slide handles being able to be actuated individually and relative to one another with one hand. The proximal end of the hose 18 is releasably connected to the housing of the handle 20. An electrically conductive connection is provided between the cannula 32 and the metal electrode cable 22 inside the handle, which is not shown in any more detail.

By a relative movement of the slide handles 34 and 38 relative to one another and relative to the hand piece 20, the metal electrode 16 can be displaced from the position shown in Fig. 2, in which it is completely located inside the hose 18, into the arrangement shown in Fig. 3, in which the metal electrode 16 projects from the distal end of the hose 18 and has a star shape.

Furthermore, a connection 40 for flushing liquid can be provided in the region of the hand piece 20, through which, for example, physiological saline can be introduced into the region of the metal electrode 16.

The hose 18 of the probe 14 consists of flexible, insulating material. The metal electrode 16 and the cannula 32 consist of a super-elastic material which is electrically conductive, for example of a nickel-titanium alloy. The adjustment element 36 can optionally be in wire form or in cannula form and can consist of flexible metal or plastic. The handle 20 and the slide handles 34, 38 consist of insulating plastic.

Depending on the application, the probe 14 can have a different total length up to approximately 200 mm and a probe diameter up to approximately 3 mm. The metal electrode 16 can have a length of approximately 20 to 35 mm. The outer diameter of the metal electrode 16 can amount, for example, to 1.8 mm. The metal electrode can be converted from the configuration shown in Fig. 2 by compression into the star-shaped arrangement shown in Fig. 3 in which the electrode star has an axial length of approximately 8 mm and a diameter of up to 30 mm.

The manufacture of the metal electrode 16 in accordance with the invention can, for example, take place in that an areal blank, for example a thin metal foil or, however, a cylindrical cannula, in each case of electrically conductive material, are provided with micro-cuts extending parallel to one another, with the cuts in each case not extending up to the rim of the blank or of the cannula at their ends. If these cuts are distributed evenly over the periphery of the cannula or over the extent of the blank, strip-like material sections are formed between the individual cuts and form the arms 26. These micro-cuts can be made in spiral shape, meander shape, zig-zag shape or wave shape in a central section (cf. Figs. 2 and 3), where-

by the above-described central sections of the arms can be formed. The blank can subsequently be shaped to form a sleeve.

It can moreover be advantageous to vary the thickness of the micro-cut along its longitudinal extent. The thickness of the micro-cuts can, for example, be selected to the larger in the central section M than in the region of the end sections, whereby an additional variation of the elasticity behavior of the arms is possible.

The function of the above-described probe will be described in the following for the example of endoluminal radio frequency thermoablation.

After the patient to be treated has been brought into contact with an adhesive and large areal neutral electrode 12 on the skin, which should take place at a body distance to the metal electrode 16 which is as short as possible, the patent is an integral component of the radio frequency circuit after the connection of the neutral electrode cable 24 to the neutral electrode 12 and to the radio frequency generator 10.

The probe in accordance with the invention is subsequently navigated to the target area via the instrumentation channel of a flexible endoscope - or with invasive therapies, using image monitoring (sonogram, computer tomogram, magnetic tomogram) via body cavities or vessels. The metal electrode 16 is subsequently moved out and unfolded by actuating the slide handles 34 and 38 such that the former contacts the biological tissue to be treated or the pathogenic biological tissue, for example inside the esophagus. A radio frequency current is subsequently activated at the RF generator for a defined time or up to the reaching of a pre-determined electrical impedance level or energy level or also temperature level. The radio frequency current flows in this process within the probe 14 via the

star-shaped unfolded metal electrode 16 to the contacted biological tissue and via the neutral electrode 12 back to the RF generator 10. Locally limited heat effects occur with the square of the RF current strength and proportionally to the current contact impedance electrode/biological tissue and proportional to the activation time, with the biological tissue being thermally denatured with reached temperatures above 50°C, preferably in the range 60°C up to 100°C. After second-long action times of the RF current, biological tissue shrinkages and drying outs are achieved in the tightly restricted contact area of the electrodes. Malign biological tissue (primary tumors, metastases) can thus also be thermally destroyed or a thermal hemostasis or even therapeutic tissue shrinkage with tolerable scar formation can be produced.

Reference symbol list

10	RF generator
12	neutral electrode
14	probe
16	metal electrode
18	hose
20	hand piece
22	metal electrode cable
24	neutral electrode cable
26	arms
28	distal end piece
30	proximal end piece
32	cannula
34	slide handle
36	adjustment element
38	slide handle
40	connection for flushing liquid
M	central region